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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/765,739
Filing Date: January 18, 2001
Appellant(s): LAWTON ET AL.

Robert Lawton, et al.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 27, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Claims on Appeal

The Appeal involves claims 21-24 and 39-42.

(5) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(6) Summary of Invention

The summary of invention contained in the brief is correct.

(7) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

Claims 39-42 are unpatentable under 35 U.S.C. 102(a).

Claims 21-24 and 39-42 are unpatentable under 35 U.S.C. 102(b).

Claims 21-24 are unpatentable under 35 U.S.C. 102(b).

The rejection of claim 21 under 35 U.S.C. 112, second paragraph is withdrawn.

(8) Grouping of Claims

Appellant's brief includes a statement that claims 21 stands or falls alone and claims 21-24 and 39-42 stand or fall together and provides reason as set forth in 37 CFR 1.192(c) (7) and (c)(8).

(9) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(10) Prior Art of Record

Waner, T. et al, *Journal of Veterinary Diagnostic Investigation, Comparison of a Clinic-based ELISA test kit with the Immunofluoresence test for the Assay or Ehrlichia canis antibodies in Dogs*, Vol.12, (2000), pp.240-244.

Cadman, T. et al, *The Veterinary Record, Comparison of the Dot-Blot Enzymes Linked Immunoassay with Immunofluorescence for Detecting Antibodies to Ehrlichia canis,* (October 8, 1994), pp.362.

WO 99/13720, 03/1999, Rikihisa et al.

(11) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 39-42 are rejected under 35 U.S.C. 102(a) as anticipated by Waner et al, *(Journal of Veterinary Diagnostic Investigation, Vol.12, (2000), pp.240-244).*

Claims 39-42 are drawn to a device containing one or more polypeptides consisting of SEQ ID Nos:3-7 that specifically bind to an anti-*Ehrlichia* antibody.

Waner et al teach the use of a device (i.e. a clinic ELISA test kit). Waner et al teach that *Ehrlichia canis* IgG antibody titers of serum samples were determined by using a commercial ELISA test kit containing plastic combs sensitized with *E. canis* antigen. Waner et al teach that the sera to be tested was incubated with the comb (containing antigen dots). Waner et al teach that after washing away unbound antibodies the combs were allowed to react with goat anti-dog IgG alkaline phosphatase conjugate. Waner et al teach that bound antibodies were detected with a precipitating chromogen, 5-bromo-4chloro-3-indolyl phosphate and nitro-blue tetrazolium. The polypeptide sequence contained on the plastic comb (i.e. device) would be inherent in the teachings of the prior art. It is well known in the art to include instructions for using

polypeptides for the identification of an *Ehrlichia* infection in a mammal in a diagnostic kit. The instructions for performing various immunoassays (i.e. western blot, reversible flow chromatographic binding assay, enzyme linked immunosorbent assay or indirect immunofluorescense assay) are well known in the art. The device of Waner, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's device with the device of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the device of the prior art does not possess the same material structural and functional characteristics of the claimed device). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

II. Claims 21-24 and 39-42 are rejected under 35 U.S.C. 102(b) as anticipated by Cadman et al, *(The Veterinary Record, (October 8, 1994, pp.362)*. It should be noted that this rejection was under 35 U.S.C. 102(b) and not 35 U.S.C. 102(a) as indicated by Appellant.

Claims 21-24 and 39-34 are drawn to a device containing one or more polypeptides consisting of SEQ ID Nos:1-7 and amino acid variants thereof that specifically bind to an anti-*Ehrlichia* antibody.

Cadman et al teach a device (i.e. a cross dot blot apparatus), nitrocellulose paper coated with *E. canis* antigen. Cadman et al teach that 0.7 μg of protein in TBS was use per dot. Cadman et al teach that test sera was incubated with the antigen (dots on nitrocellulose paper). Cadman et al teach that the bound antibody was detected with

peroxidase-labeled goat anti-dog IgG and 4-chloronaphthol. The polypeptide sequence contained on the nitrocellulose membrane (i.e. device) would be inherent in the teachings of the prior art. It is well known in the art to include instructions for using polypeptides for the identification of an *Ehrlichia* infection in a mammal in a diagnostic kit. The instructions for performing various immunoassays (i.e. western blot, reversible flow chromatographic binding assay, enzyme linked immunosorbent assay or indirect immunofluorescense assay) are well known in the art. The device of Cadman, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's device with the device of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the device of the prior art does not possess the same material structural and functional characteristics of the claimed device). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

III. Claims 21-24 are rejected under 35 U.S.C. 102(b) as anticipated by Rikihisia et al *(WO 99/13720, 03/1999).*

Claims 21-24 are drawn to a device that containing one or more polypeptides consisting of SEQ ID Nos:1-7 and amino acid substitution variants thereof that specifically bind to an anti-*Ehrlichia* antibody.

Rikihisia et al teach devices such as columns, plastic dishes and membranes that contain the *Ehrlichia* polypeptides and peptide of the invention for using in

serodiagnosing ehrlichiosis in mammals (see the Abstract and page 11). Rikihisia et al teach an amino acid variant of SEQ ID NO:7 has 85% identity to SEQ ID NO:7 (see Figure 19B). Rikihisia et al anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's device with the device of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the device of the prior art does not possess the same material structural and functional characteristics of the claimed device). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

(11) Response to Arguments

Response to Arguments Traversing the Rejection of claims 39-42 under 35 U.S.C.102(a)(Waner et al.).

Appellant urges that Waner et al teach whole *E. canis* proteins and cell and does not teach or suggest the use of any types of *E. chaffeensis* polypeptides in a device nor does Waner et al teach *E. chaffeensis*-derived polypeptides. Appellant urges that Waner et al do not specifically teach or suggest the use of distinct polypeptide as shown in SEQ ID NOs.3-7 nor does Waner et al teach amino acids that are 18 to 20 amino acids in length. Appellant urges that the claimed invention is not anticipated by Waner et al. Appellant urges that Waner et al teach an immunofluorescence antibody test (IFA) and ELISA for *E. canis*. Appellant urges that Waner et al teach entire cells or whole proteins as assay antigens, and cannot teach, suggest or inherently disclose the

specific individual polypeptides shown in SEQ ID NOs. 3-7. Appellant urges that Waner et al do not identify the polypeptide fragments to be of any particular diagnostic use.

Appellant urges that there is no teaching in Waner et al directly or inherently that would direct one skilled in the art to the particular defined sequences of SEQ ID NOs. 3-7 or specified variants for any reason. Appellant urges that Waner et al do not teach or suggest that polypeptides of SEQ ID NOs 3-7 would be useful as individual polypeptides apart from entire *E. canis* infected cells or entire proteins. Appellant urges that Waner et al provide no recognition or suggestion that the distinct polypeptides shown in SEQ ID Nos. 1-3 or any other polypeptide fragments would be of diagnostic use. Appellant urges that Waner et al reagents are impure reagents which the instant specification teaches are of limited usefulness due to the sensitivity and specificity issues. Appellant urges that the claimed device provides greater sensitivity and specificity than reagents used in Waner et al. Appellant urges that the specification (Example 1) teaches assays which use synthetic peptides were more sensitive and specific than assays that use native *E. canis* antigens. Appellant refers to the Declaration filled under 37 C.F.R. 1.132 (Declaration of Dr. Chandrashekar) to point out that the devices of the claimed invention are more sensitive than that of the prior art and that the compositions of the prior art are entire cells or whole proteins that are impure.

The claims are drawn to a device which contains one or more polypeptides selected from the group consisting of SEQ ID Nos. 3-7 that specifically bind to an anti-*Ehrlichia* antibody.

The Examiner is interpreting the device to contain polypeptides that bind to anti-*Ehrlichia* antibody. Therefore, the claims read on the whole cells and whole proteins. While claim 24 specifies *E. canis* or *E. chaffeensis*, it is only within the context of identifying an infection. The claims do not require that the polypeptides are derived from any *Ehrlichia* species. Moreover, the Examiner is viewing the device to read on an apparatus and not a reagent inasmuch as the claims recite a device containing the polypeptides. It is the Examiner's position that Waner et al reads on the claimed invention because the device could contain more than one polypeptide since the claims recites open claim language. There are not specific limitations in the claims that the amino acid sequences are between 18 to 20 amino acids in length. To address Appellants comments regarding the Declaration of Dr. Chandrashekar, which is directed to issues regarding sensitivity and specificity, it should be remembered that there are no limitations in the claims requiring that the devices require any particular level of sensitivity nor are there limitations in the claims regarding the level of purity. It is noted that the features upon which Appellant relies (i.e., purity or sensitivity) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, Dr. Chandrashekar is not sufficient overcome to the instant rejection.

Response to Arguments Traversing the Rejection of claims 21-24 and 39-42 under 35 U.S.C.102(b)(Cadman et al.).

Appellant urges that SEQ ID NOs: 3-7 are derived from *E. chaffeensis* and Cadman et al do not teach any *E. chaffeensis* sequences. Appellant urges that Cadman et al cannot anticipate the claimed invention. Appellant urges that Cadman et al teach whole *E. canis* proteins and whole cells. Cadman et do not teach the use of distinct polypeptide as shown in SEQ ID NOs.1-7 nor does Cadman et al teach amino acid sequences that are 18 to 20 amino acids in length.

Appellant urges that Cadman et al teach an dot-blot enzyme linked immunoassay with immunofluorescence antibody test (IFA) and ELISA for *E. canis*. Appellant urges that Cadman et al teach that entire cells or whole proteins as assay antigens. Appellant urges that Cadman et al cannot teach, suggest or inherently disclose the specific individual polypeptides shown in SEQ ID NOs. 1-7 or specified. Appellant urges that Cadman et al do not identify the polypeptide fragments to be of any particular diagnostic use. Appellant urges that there is no teaching in Cadman et al directly or inherently that would direct one skilled in the art to the particular defined sequences of SEQ ID NOs. 1-7 or specified variants for any reason. Appellant urges that Cadman et al do not teach or suggest that polypeptides of SEQ ID NOs. 1-7 would be useful as individual polypeptides apart from entire *E. canis* infected cells or entire proteins. Appellant urges that Cadman et al provide no recognition or suggestion that the distinct polypeptides shown in SEQ ID Nos. 1-7 or any other polypeptide fragments would be of diagnostic use. Appellant urges the invention provides that highly purified

reagents for detection of *Ehrlichia*, that is polypeptides of about 18 to 20 amino acids whereas Cadman et al teach whole infected cells or whole *E. canis* proteins. Appellant urges that Cadman et al reagents are impure reagents which the instant specification teaches are of limited usefulness due to the sensitivity and specificity issues. Appellant urges that the claimed device provides greater sensitivity and specificity than reagents used in Cadman et al. Appellant urges that the specification (Example 1) teaches that assays that use synthetic peptide of the invention were more sensitive and specific than assays that use native *E. canis* antigens. Appellant refers to the Declaration filled under 37 C.F.R. 1.132 (Declaration of Dr. Chandrashekar) to point out that the devices of the claimed invention are more sensitive than that of the prior art and that the compositions of the prior art are entire cells or whole proteins that are impure.

Claims 21-24 are drawn to a device which contains one or more polypeptides selected from the group consisting of SEQ ID Nos. 1-7 and amino acid substitution variants that specifically bind to an anti-*Ehrlichia* antibody. It should be noted that claims 39-42 are only directed to a device that contains one or more polypeptides selected from the group consisting of SEQ ID NOs. 3-7 that specifically bind to an anti-*Ehrlichia* antibody.

The Examiner is interpreting the claims to read on a device comprising one or more polypeptides as well as substitution variants that bind to anti-*Ehrlichia* antibody. Therefore, the claims read on the whole cells and whole proteins. While claims 24 and 42 specifies *E. canis* or *E. chaffeensis*, it is only within the context of identifying an infection. The claims do not require that the polypeptides are derived from any *Ehrlichia*

species. Moreover, the Examiner is viewing the device to read on an apparatus and not a reagent inasmuch as the claims recite a device containing the polypeptides. It is the Examiner's position that Cadman et al reads on the claimed invention because the device could contain more than one polypeptide since the claims recites open claim language. There are not specific limitations in the claims that the amino acid sequences are between 18 to 20 amino acids in length. To address Appellants comments regarding the Declaration of Dr. Chandrashekar, which is directed to issues regarding sensitivity and specificity, it should be remembered that there are no limitations in the claims requiring that the devices require any particular level of sensitivity nor are there limitations in the claims regarding the level of purity. It is noted that the features upon which Appellant relies (i.e., purity or sensitivity) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, Dr. Chandrashekar is not sufficient overcome to the instant rejection.

Response to Arguments Traversing the Rejection of claims 21-24 under 35 U.S.C.102(b)(Rikihisa et al.).

Appellant urges that Rikihisa et al do not teach or suggest an element of the claims, that is one or more polypeptides consisting of SEQ ID NOs: 1-7. Appellant urges that Rikihisa et al cannot anticipate the claimed invention. Appellant urges that the claims recite an *E. canis* polypeptide fragment. Appellant urges that the polypeptide fragments are useful to detect *Ehrlichia* antibodies. Appellant asserts that the polypeptide fragments are useful to detect *Ehrlichia* antibodies. It should be remembered that the claims are directed to a device (a product) and not a method using the product. It should be noted that using the claimed device to detect antibodies is viewed as intended use of the product. It is the Examiner's position that Rikihisa et al anticipate the claimed invention.

Appellant urges the Office asserts that the full-length proteins taught by Rikihisa et al would read on the claimed polypeptide fragments. Appellant urges that the addition of amino acids to the polypeptides so they encompass the whole proteins of Rikihisa would materially affect the characteristics of the polypeptides. Appellant urges that the use of full-length polypeptides would result in assays that are less sensitive than those disclosed in the instant specification. Appellant urges that claims cannot be read so that the whole proteins of Rikihisa et al read the claimed fragments. Appellant urges that Rikihisa et al do not teach particular fragments of *E. canis* and *E. chaffeenis*. Appellant refers to the Declaration filled under 37 C.F.R. 1.132 (Declaration of Dr.

Chandrashekar) to point out that the devices of the claimed invention are more sensitive than that of the prior art and that the compositions of the prior art are entire cells or whole proteins that are impure.

As stated above, the Examiner is interpreting the claims to read on a device comprising one polypeptide or more than one polypeptide as well as substitution variants. The Examiner is interpreting the device to contain any polypeptide and substitution variants that binds to an anti-*Ehrlichia* antibody. Rikihisa et al teach a substitution variant of SEQ ID NO:7. All comments made in the Examiner's traversals as set forth above apply to the arguments regarding Rikihisa et al. Based on the Examiner's traversal as set forth above, it the Examiner's position that Rikihisa et al reads on the claimed invention.

Examiner's Answer Conclusion

For the above reasons, it is believed Examiner should be affirmed.

Respectfully submitted,

Vanessa L. Ford
October 28, 2004

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